REMARKS/ARGUMENTS

Claims 1-3 and 5-10 are pending in this application. Claims 5-10 have been added. Claim 4 has been canceled.

Claim Rejections- 35 U.S.C. § 112

The Examiner has rejected claims 1 and 4 under 35 U.S.C. § 112, second paragraph, as failing to comply with the enablement requirement because the Examiner alleges that the terms "means for combining" and "means for transferring" are unclear. To facilitate prosecution, Applicants have deleted "means for combining" from claim 1 and canceled claim 4. Applicants reserve the right to pursue this subject matter in a divisional or continuation application.

Claim Rejections- 35 U.S.C. § 103

The Examiner has rejected claims 1-2 and 4 as obvious under 35 U.S.C. § 103 over Craft in view of Remmington. (Please note that the Examiner refers to the reference Clarke et al. on page 2 of the Office Action-- no citation given-- for this rejection but refers to Craft (1989) as cited in Applicants' information disclosure statement when describing the detailed basis for the rejection on page 3. Applicants believe the citation of Clarke et al. to be a typographical error and thus respond to the Craft below).

Craft et al (1989) teach the intravesicular administration of resiniferatoxin to rats via a chronic cannula into the bladder at concentrations between 0.1-10 nmol. The pending claims have been amended to recite administration to humans. Applicants have amended the claims to expedite prosecution and reserve the right to file additional claims in a continuation or divisional application.

The present invention is based on findings that resulted from a clinical trial of human patients that were diagnosed with different types of urinary incontinence and treated via intravesicular instillation of resiniferatoxin (RTX). RTX was known to have similar effects to capsaicin (CAP), which had been tested in humans. However, CAP is not suitable for routine usage in incontinence because there is intense burning and pain in the lower abdomen upon instillation, and there is a period of 2-4 days after treatment when symptoms actually deteriorate

before any improvement is noted. A major unexpected advantage of the use of RTX or its analog is that when administered at effective dosage the compounds do not cause pain or burning sensations, such as are associated with CAP treatment. Furthermore, patients experience no initial deterioration of their symptoms as is the case with CAP treatment. The therapy is therefore more tolerable and longer-lasting, compared to CAP treatment. The administration of RTX to humans that exhibit incontinence was necessary to determine an appropriate dosage range and establish whether or not the treatment would be tolerable; this information could only be obtained through human testing.

Further, as stated in Craft on page 484, "To date there are no reports on the effects of RTX in humans….. Further studies are underway to compare the long term desensitizing effects of CAP versus RTX in the rat bladder." Therefore, Craft's teaching that RTX can be administered to rats at concentrations between 0.1-10 nmol do not render obvious the pending claims to a kit containing resiniferatoxin, tinyatoxin, 20-homovanillyl-mezerein and 20-homovanillyl-12-deoxyphorbol-13-phenylacetate at a concentration of 0.05 μM to 2.0 μM that can be administered intravesicularly to a human patient.

Remington teaches the administration of fluid intravenously via a two container system. However, the pending claims are directed to a kit for the intravesicular (i.e. administration to the bladder) administration of resiniferatoxin, tinyatoxin, 20-homovanillyl-mezerein and 20-homovanillyl-12-deoxyphorbol-13-phenylacetate to a human patient. Thus, the deficiencies of Craft are not overcome by Remington.

The Examiner has rejected claims 1-2 and 4 as obvious under 35 U.S.C. § 103 over Blumberg (US Patent No. 5,021,450) in view of Remmington.

The '450 patent teaches a new class of compounds, including RTX and other homovanilloids, that have capsaisin-like effects to desensitize sensory afferent nerve fibers. The '450 patent teaches that these compounds can be administered by topical, intravenous, intraperitoneal, oral or subcutaneous routes and that the compounds should be administered at ranges between 0.0001% to 1% by weight. The '450 patent does not teach, suggest or render obvious a kit containing resiniferatoxin, tinyatoxin, 20-homovanillyl-mezerein and 20-homovanillyl-12-deoxyphorbol-13-phenylacetate at a concentration of 0.05 μM to 2.0 μM that

can be administered intravesicularly to a human patient as presently claimed. Further, as discussed above, Remington does not overcome the deficiencies of the '450 patent.

It is respectfully believed that this application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Other than the petition fee, no additional fees are believed to be due in connection with this response. However, should the Commissioner determine otherwise, he is authorized to charge such fees and credit any overpayment to Deposit Account No. 11-0980.

Respectfully submitted,

KING & SPALDING LLP

By _____
Rebecca Kaufman
Reg. No. 44,819
Tel.: (404) 572-4600

KING & SPALDING LLP
34th Floor
1180 Peachtree Street, N.E.
Atlanta, Georgia 30309-3521